REMARKS

Claims 28, 29, 31, 32 and 44-47 are pending. Claims 28, 29, 31, 32 and 44-47 are presented for further consideration.

The cross-reference to related applications has been corrected as requested. Applicant has made the changes with reference to the version presented on December 28, 2009.

The examiner has made a request for Information under 37 CFR 1.131. Applicant has searched for relevant documents in response to the queries, and has found none. A declaration of Dr. David Goldenberg is forwarded herewith in response to the examiner's queries.

The rejection of claims 28, 29, 31, and 32 are rejected under Section 102(b) based on Harris *et al.* (WO 94/09136, published 4/28/1994) has been maintained, and also applied to claims 44-47. Applicant previously forwarded a Rule 131 declaration of Dr. Hans Hansen, one of the inventors. showing that applicant had reduced the present invention to practice prior to the effective date of the cited Harris document. In addition, applicant presented the declaration of Mr. Bryan Wilson, documenting attempts to obtain a similar declaration from Dr. Leung, the other co-inventor.

However, the examiner has maintained the rejection in the absence of a signed declaration of the other inventor, Leung, who is no longer employed by Immunomedics and has not returned an executed declaration for filing in this case. Accordingly, applicant now petitions under 37 CFR 1.183 for a suspension of the rules requiring signatures of both inventors. This course of action is set forth in MPEP 715.04. In order to allow time for a decision on this petition, applicant is filing a Request for Continued Examination.

As previously noted, the declaration of Dr. Hansen is sufficient to establish prior reduction to practice of the presently claimed subject matter, thereby removing Harris as a reference. The examiner has not set forth any substantive basis for maintaining the rejection based on Harris, merely the procedural one based on the absence of Dr. Leung's declaration. Accordingly, no further comment is necessary on the part of applicant.

Claims 44-47 are rejected under Section 102(b) based on Adair *et al.* (WO 91/09967). The examiner cites Adair (WO 91/09967) as teaching a method of designing humanized heavy and light chain variable domain amino acid sequences of murine monoclonal antibody B72.3 comprising comparing the light and heavy chain variable domain sequences ofB72.3 with the light and heavy

chain sequences of two or more human antibodies (e.g., those in Kabat), wherein the human REI light chain frameworks are selected and the human EU heavy chain frameworks are selected for FR1, FR2 and FR3 and a human consensus heavy chain FR4 was selected and the selected human frameworks are incorporated with the corresponding light and heavy chain CDRs ofB72.3 and the light chain mouse residue at position 48 (2 amino acids from CDR2) and the heavy chain mouse residues at position 73, which is close to both CDRs 1 and 3 and could have a detrimental effect on antigen binding were retained in the humanized B72.3 antibody (i.e., residues predicted to have contacts with the CDRs and within a 4.5 Angstrom radius of any atoms within the CDRs).

Adair did not compare the amino acid sequences of the light and heavy chain variable domains of a monoclonal antibody to be humanized with the amino acid sequences of the light and heavy chain variable domains of two or more human antibodies, then select framework regions from a first human antibody for the light chain and from second and third human antibodies for the heavy chain based on the sequence comparison, wherein the heavy chain FR1, FR2 and FR3 are selected from the second human antibody and FR4 is selected from the third human antibody, and then incorporate the framework regions selected with the corresponding light and heavy chain complementarity determining regions of the monoclonal antibody to be humanized, to design a humanized light and heavy chain variable domain amino acid sequences. Adair used a concensus FR4, and therefore does not teach “FR4 is selected from the third human antibody” as presently claimed. On this basis alone, the rejection under Section 102 must fail.

There is nothing in the currently cited Adair published PCT application examples pursuant to humanization of B72.3 that would have anticipated the present claims. Adair only relates to development of chimeric antibodies. Adair provides no information in WO 91/09967 relating to a humanized mab having the properties of murine or chimeric B72.3.

In response to this rejection based on Adair, Dr. Hansen has searched extensively for any *other* information of a humanized B72.3 antibody. He has gone through over 600 abstracts that surfaced when searching for B72.3 as the sole search term on PubMed, and performed additional Delphion patent searches. He also looked on the EPO Registry for the corresponding European application (EP0329755). However, the European application was withdrawn and the EP file wrapper was destroyed.

In short, Dr. Hansen could find nothing regarding the Adair "humanized" B72.3 mab. After significant effort, Dr. Hansen can find no follow-up to the cited Adair published PCT application to

provide data on the "purported" humanization of B72.3 mab, even by the inventors of the B72.3 mab. It would appear that specific information on the affinity or specificity of a humanized B72.3 Mab was never made public by Adair, if indeed one actually was made. Accordingly, it is submitted that claims 44 to 47 are patentable over the cited Adair document.

If there are any problems with this response, or if the examiner believes that a telephone interview would advance the prosecution of the present application, Applicant's attorney would appreciate a telephone call. In view of the foregoing, it is believed none of the references, taken singly or in combination, disclose the claimed invention. Accordingly, this application is believed to be in condition for allowance, the notice of which is respectfully requested.

Respectfully submitted,

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DATE

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